

PCT

国際予備審査報告

(法第12条、法施行規則第56条)
〔PCT36条及びPCT規則70〕

REC'D 17 JUL 1998

WIPO PCT

出願人又は代理人 の書類記号 660348	今後の手続きについては、国際予備審査報告の送付通知（様式PCT/ IPEA/416）を参照すること。	
国際出願番号 PCT/JP97/01893	国際出願日 (日.月.年) 04.06.97	優先日 (日.月.年) 07.06.96
国際特許分類 (IPC) Int.Cl ⁸ - C12N15/12, A61K31/70, C12N5/10, C07K14/82, C07K16/32		
出願人 (氏名又は名称) 伊東 恭悟		

1. 国際予備審査機関が作成したこの国際予備審査報告を法施行規則第57条 (PCT36条) の規定に従い送付する。

2. この国際予備審査報告は、この表紙を含めて全部で 3 ページからなる。

- ☐ この国際予備審査報告には、附属書類、つまり補正されて、この報告の基礎とされた及び/又はこの国際予備審査機関に対してした訂正を含む明細書、請求の範囲及び/又は図面も添付されている。
(PCT規則70.16及びPCT実施細則第607号参照)
この附属書類は、全部で ページである。

3. この国際予備審査報告は、次の内容を含む。

- I ☒ 国際予備審査報告の基礎
- II ☐ 優先権
- III ☐ 新規性、進歩性又は産業上の利用可能性についての国際予備審査報告の不作成
- IV ☐ 発明の単一性の欠如
- V ☒ PCT35条(2)に規定する新規性、進歩性又は産業上の利用可能性についての見解、それを裏付けるための文献及び説明
- VI ☐ ある種の引用文献
- VII ☐ 国際出願の不備
- VIII ☐ 国際出願に対する意見

国際予備審査の請求書を受理した日 27.10.97	国際予備審査報告を作成した日 07.07.98	
名称及びあて先 日本国特許庁 (IPEA/JP) 郵便番号100-8915 東京都千代田区霞が関三丁目4番3号	特許庁審査官 (権限のある職員) 滝本 晶子	4B 9452
電話番号 03-3581-1101 内線 3449		

I. 国際予備審査報告の基礎

1. この国際予備審査報告は下記の出願書類に基づいて作成された。(法第6条(PCT14条)の規定に基づく命令に
 応答するために提出された差し替え用紙は、この報告書において「出願時」とする)

☒ 出願時の国際出願書類

- | | | |
|--------------------------------|----------------|----------------------|
| <input type="checkbox"/> 明細書 | 第 _____ ページ、 | 出願時のもの |
| <input type="checkbox"/> 明細書 | 第 _____ ページ、 | 国際予備審査の請求書と共に提出されたもの |
| <input type="checkbox"/> 明細書 | 第 _____ ページ、 | _____ 付の書簡と共に提出されたもの |
| <input type="checkbox"/> 明細書 | 第 _____ ページ、 | _____ 付の書簡と共に提出されたもの |
| <input type="checkbox"/> 請求の範囲 | 第 _____ 項、 | 出願時に提出されたもの |
| <input type="checkbox"/> 請求の範囲 | 第 _____ 項、 | PCT19条の規定に基づき補正されたもの |
| <input type="checkbox"/> 請求の範囲 | 第 _____ 項、 | 国際予備審査の請求書と共に提出されたもの |
| <input type="checkbox"/> 請求の範囲 | 第 _____ 項、 | _____ 付の書簡と共に提出されたもの |
| <input type="checkbox"/> 請求の範囲 | 第 _____ 項、 | _____ 付の書簡と共に提出されたもの |
| <input type="checkbox"/> 図面 | 第 _____ ページ/図、 | 出願時に提出されたもの |
| <input type="checkbox"/> 図面 | 第 _____ ページ/図、 | 国際予備審査の請求書と共に提出されたもの |
| <input type="checkbox"/> 図面 | 第 _____ ページ/図、 | _____ 付の書簡と共に提出されたもの |
| <input type="checkbox"/> 図面 | 第 _____ ページ/図、 | _____ 付の書簡と共に提出されたもの |

2. 補正により、下記の書類が削除された。

- ☐ 明細書 第 _____ ページ
☐ 請求の範囲 第 _____ 項
☐ 図面 第 _____ ページ/図

3. ☐ この国際予備審査報告は、補充欄に示したように、補正が出願時における開示の範囲を越えてされたものと認められるので、その補正がされなかったものとして作成した。(PCT規則70.2(c))

4. 追加の意見(必要ならば)

V. 新規性、進歩性又は産業上の利用可能性についての法第12条（PCT35条(2)）に定める見解、それを裏付ける文献及び説明

1. 見解

新規性 (N)

請求の範囲 1-11 有
請求の範囲 無

進歩性 (IS)

請求の範囲 1-11 有
請求の範囲 無

産業上の利用可能性 (IA)

請求の範囲 1-11 有
請求の範囲 無

2. 文献及び説明

請求の範囲 1～11 に記載された発明は、国際調査報告に表示された文献及び当該発明に関連があると認められる文献に記載されておらず、当業者にとって自明なものでもない。

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing: 11 December 1997 (11.12.97)	
International application No.: PCT/JP97/01893	Applicant's or agent's file reference: 660348
International filing date: 04 June 1997 (04.06.97)	Priority date: 07 June 1996 (07.06.96)
Applicant: ITOH, Kyogo et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International preliminary Examining Authority on:
27 October 1997 (27.10.97)☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer: J. Zahra Telephone No.: (41-22) 338.83.38
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19/202047
PATENT COOPERATION TREATY 5060

PCT/JP97/01893

PCT

NOTIFICATION CONCERNING
DOCUMENT TRANSMITTED

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year)

20 November 1998 (20.11.98)

International application No.

PCT/JP97/01893

International filing date (day/month/year)

04 June 1997 (04.06.97)

Applicant

ITOH, Kyogo et al

The International Bureau transmits herewith the following documents and number thereof:

_____ copy of the English translation of the international preliminary examination report (Article 36(3)(a))

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Sean Taylor

Telephone No.: (41-22) 338.83.38

(translation)

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page.

NAME AND ADDRESS
OF DEPOSITOR

NAME: Kyogo ITOH

ADDRESS: 2-25-9, Keyaki-dai, Kiyama-cho,
Miyaki-gun, Saga-ken

1. IDENTIFICATION OF THE MICROORGANISMS	
Identification reference given by the DEPOSITOR E. coli JM109 (K3)	(Deposit No.) FERM BP-5951
2. SCIENTIFIC DESCRIPTION AND PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under 1 above was accompanied by: <input type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation	
3. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism as identified under 1 above, which was received by it on May 22, 1997 (dated of the original deposit).	
4. RECEIPT OF REQUEST FOR TRANSFER	
This International Depositary Authority received the microorganism as recited in the above item 1 on (dated of the original deposit) and then received a request for transfer the original deposit to International deposition under Budapest Treaty on	
5. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology Michio OISHI, Dr., DIRECTOR GENERAL. Address: 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305, JAPAN May 23, 1997	



特許手続上の微生物の寄託の国際的承認
に関するブダペスト条約

下記国際寄託当局によって規則 7. 1 に従い
発行される。

原寄託についての受託証

氏名 (名称)

伊東 恭悟

殿

寄託者

あて名 千

佐賀県三養基郡基山町けやき台 2-25-9

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

1. 微生物の表示

(寄託者が付した識別のための表示)

E. coli JM109 (K3)

(受託番号)

FERM BP- 5951

2. 科学的性質及び分類学上の位置

1 欄の微生物には、次の事項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

3. 受領及び受託

本国際寄託当局は、平成 9 年 5 月 22 日 (原寄託日) に受領した 1 欄の微生物を受託する。

4. 移管請求の受領

本国際寄託当局は、年 月 日 (原寄託日) に 1 欄の微生物を受領した。
そして、年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名称: National Institute of Bioscience and Human-Technology
Agency of Industrial Science and Technology

所長 大石 道夫

Michio Oishi, DIRECTOR GENERAL.

あて名: 日本国茨城県つくば市東 1 丁目 1 番 3 号 (郵便番号 305)
1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken
305, JAPAN

平成 9 年 (1997) 5 月 23 日

(translation)

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page.

NAME AND ADDRESS
OF DEPOSITOR

NAME: Kyogo ITOH

ADDRESS: 2-25-9, Keyaki-dai, Kiyama-cho,
Miyaki-gun, Saga-ken

1. IDENTIFICATION OF THE MICROORGANISMS	
Identification reference given by the DEPOSITOR KE-4CTL	(Deposit No.) FERM BP-5954
2. SCIENTIFIC DESCRIPTION AND PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by: ■ a scientific description ■ a proposed taxonomic designation	
3. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism as identified under 1 above, which was received by it on May 23, 1997 (dated of the original deposit).	
4. RECEIPT OF REQUEST FOR TRANSFER	
This International Depositary Authority received the microorganism as recited in the above item 1 on , (dated of the original deposit) and then received a request for transfer the original deposit to International deposition under Budapest Treaty on , .	
5. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology Michio OISHI, Dr., DIRECTOR GENERAL. Address: 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305, JAPAN May 23, 1997	



特許手続上の微生物の寄託の国際的承認
に関するブタベスト条約

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
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下記国際寄託当局によって規則 7. 1 に従い
発行される。

issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this
page.

原寄託についての受託証

氏名 (名称)

伊東 恭悟

寄託者

あ て 名 氏

殿

佐賀県三養基郡基山町けやき台 2-25-9

1. 微生物の表示

(寄託者が付した識別のための表示)
KE-4CTL

(受託番号)
FERM BP- 5954

2. 科学的性質及び分類学上の位置

1 欄の微生物には、次の事項を記載した文書が添付されていた。

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- ☒ 分類学上の位置

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そして、年 月 日に原寄託よりブダベスト条約に基づく寄託への移管請求を受領した。

5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名称: National Institute of Bioscience and Human-Technology
Agency for Industrial Science and Technology

所長 大石 道夫

Michio Ohtsu, DIRECTOR GENERAL.

あて名: 日本国茨城県つくば市東 1 丁目 1 番 3 号 (郵便番号 305)
1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken
305, JAPAN

平成 9 年 (1997) 5 月 23 日

(translation)

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL
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NAME AND ADDRESS
OF DEPOSITOR

NAME: Kyogo ITOH

ADDRESS: 2-25-9, Keyaki-dai, Kiyama-cho,
Miyaki-gun, Saga-ken

1. IDENTIFICATION OF THE MICROORGANISMS	
Identification reference given by the DEPOSITOR esophageal cancer cell line KE-4	(Deposit No.) FERM BP-5955
2. SCIENTIFIC DESCRIPTION AND PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under 1 above was accompanied by: <input type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation	
3. RECEIPT AND ACCEPTANCE	
This International Depositary Authority accepts the microorganism as identified under 1 above, which was received by it on May 23, 1997 (dated of the original deposit).	
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This International Depositary Authority received the microorganism as recited in the above item 1 on _____, (dated of the original deposit) and then received a request for transfer the original deposit to International deposition under Budapest Treaty on _____.	
5. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology Michio OISHI, Dr., DIRECTOR GENERAL Address: 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305, JAPAN May 23, 1997	

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

特許手続上の微生物の寄託の国際的承認に関するブダペスト条約

下記国際寄託当局によって規則 7. 1 に従い発行される。

原寄託についての受託証

issued pursuant to Rule 7. 1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

氏名 (名称)

伊東 恭悟

寄託者

あて名 〒

殿

佐賀県三養基郡基山町けやき台 2-25-9

1. 微生物の表示	
(寄託者が付した識別のための表示) 食道癌細胞株 KE-4	(受託番号) FERM BP- 5955
2. 科学的性質及び分類学上の位置	
1 欄の微生物には、次の事項を記載した文書が添付されていた。 <input checked="" type="checkbox"/> 科学的性質 <input checked="" type="checkbox"/> 分類学上の位置	
3. 受領及び受託	
本国際寄託当局は、平成 9 年 5 月 23 日 (原寄託日) に受領した 1 欄の微生物を受託する。	
4. 移管請求の受領	
本国際寄託当局は、年 月 日 (原寄託日) に 1 欄の微生物を受領した。 そして、年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。	
5. 国際寄託当局	
<p>通商産業省工業技術院生命工学工業技術研究所</p> <p>名称: National Institute of Advanced Industrial Science and Technology Agency of Industrial Science and Technology</p> <p>所長 大石 道夫 Michio Oishi, DIRECTOR GENERAL.</p> <p>あて名: 日本国茨城県つくば市東 1 丁目 1 番 3 号 (郵便番号 305) 1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken 305, JAPAN</p>	
平成 9 年 (1997) 5 月 23 日	

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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 660348	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP97/01893	International filing date (day/month/year) 04 June 1997 (04/06/97)	Priority date (day/month/year) 07 June 1996 (07/06/96)
International Patent Classification (IPC) or national classification and IPC C12N 15/12, A61K 31/70, C12N 5/10, C07K 14/82, C07K 16/32		
Applicant ITO, Kyogo		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 27 October 1997 (27/10/97)	Date of completion of this report 07 July 1998 (07/07/98)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP97/01893

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

- ☒ the international application as originally filed.
- ☐ the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.
- ☐ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.
- ☐ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP97/01893

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

The inventions of claims 1-11 are neither disclosed in any of the documents cited in the ISR nor in the documents considered to be relevant to the present inventions, and they are non-obvious to a person skilled in the art.

e.g. expression vectors, the necessary common attribute is the ORF (SEQ ID NO: 2).

Weighing all factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2.

Conclusion: The written description requirement is satisfied.

Example 9: Hybridization

Specification: The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of cDNAs that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

Claim:

An isolated cDNA that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1,

wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

Analysis:

A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO: 1 under highly stringent conditions and encodes a protein with a specific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing.

The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity.

The search of the prior art indicates that SEQ ID NO: 1 is novel and unobvious.

There is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the claimed genus.

There is actual reduction to practice of the disclosed species.

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of

skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Conclusion: The claimed invention is adequately described.